DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 26, 2015

SPINEART
Mr. Franck Pennesi
Director of Industry & Quality
International Center Cointrin
20 Route De Pre-bois-CP 1813
1215 Geneva
Switzerland

Re: K143214
Trade/Device Name: SCARLET® AC-T
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: February 23, 2015
Received: February 23, 2015

Dear Mr. Pennesi:

This letter corrects our substantially equivalent letter of February 23, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143214

Device Name
SCARLET®AC-T

Indications for Use *(Describe)*
The SCARLET®AC-T is intended to be used as an intervertebral body fusion cage as a standalone system used with the two bone screws provided and requires no additional supplementary fixation systems. It is inserted between the vertebral bodies into the disc space from levels C2 to T1 for the treatment of cervical degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The device system is designed for use with autograft bone to facilitate fusion. SCARLET®AC-T is intended to be used at one level. The cervical cage is to be used in a skeletally mature patient who has had six weeks of non-operative treatment prior to implantation of the cage.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Traditional 510k
SCARLET® AC-T
Secured Anterior Cervical Cage

510(k) SUMMARY

510k	TRADITIONAL
Basis for submission	Extension of the range of SCARLET® AC-T devices cleared under K141314
Submitted by	SPINEART International Center Cointrin 20 route de pré-bois CP1813 1215 GENEVA 15 SWITZERLAND
Contacts	Franck PENNESI Director of Industry & Quality Phone : +41 22 799 40 25 Fax : +41 22 799 40 26 Mail : fpennesi@spineart.com Regulatory contact : Dr Isabelle DRUBAIX (Idée Consulting) idrubaix@nordnet.fr
Date Prepared	February 23rd 2015
Common Name	Intervertebral body fusion device
Trade Name	SCARLET® AC-T
Classification Name	Intervertebral Fusion Device With Integrated Fixation, Cervical
Class	II
Product Code	OVE
CFR section	888.3080
Device panel	ORTHOPEDIC
Legally marketed predicate devices	Primary Predicate device: SCARLET® AC-T (K141314) manufactured by SPINEART Additional predicates include: STALIF C® Cervical Intervertebral Body Fusion Cage (K120819) manufactured by CENTINEL SPINE, INC; Chesapeake® cervical-Ti Stabilization system (K111439) manufactured by K2M, INC; Zero-P anterior cervical interbody fusion device (K112459) manufactured by SYNTHES SPINE; AVS® Anchor-C Cervical Cage System (K102606) manufactured by STRYKER SPINE
Description of the device	Similar to the previously cleared Scarlet® AC-T Spinal System (K141314), the added Scarlet® AC-T implant is a cervical Intervertebral Body Fusion device with integrated Fixation. It consists of an interbody cage intended to be used with the two bone screws provided as a stand-alone system and requires no additional supplementary fixation system. Similar to the previously cleared Scarlet® AC-T Spinal System (K141314), the added Scarlet® AC-T implant is a box-shaped spacer with a central cavity that can be filled with bone graft (autograft) to facilitate fusion and with two cancellous bone screws that pass through screw holes within its body. The added Scarlet® AC-T intervertebral body fusion spacer comes in various sizes in order to accommodate different patient anatomies.
Indications for use	The SCARLET® AC-T is intended to be used as an intervertebral body fusion cage as a standalone system used with the two bone screws provided and requires no additional supplementary fixation systems. It is inserted between the vertebral bodies into the disc space from levels C2 to T1 for the treatment of cervical degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The device system is designed for use with autograft bone to facilitate fusion. SCARLET® AC-T is intended to be used at one level. The cervical cage is to be used in a skeletally mature patient who has had six weeks of non-operative treatment prior to implantation of the cage.

Technological Characteristics	The added SCARLET® AC-T cervical spacers are available in two footprints (small and large) and six heights (from 5 to 10 mm). The added SCARLET® AC-T cervical spacers are all made of Titanium alloy Ti6Al4V ELI conforming to ISO 5832.3 and ASTM F136. The SCARLET® AC-T cancellous bone screws are available in two diameters (3 and 3.5 mm) and four lengths (from 12 to 18 mm). The SCARLET® AC-T cancellous bone Screws are all made of Titanium alloy Ti6Al4V ELI conforming to ISO 5832.3 and ASTM F136. SCARLET® AC-T (spacer and screw) is single-use device provided sterile and supplied with dedicated surgical instruments.
Discussion of Testing	The following non-clinical tests were conducted: Static and dynamic axial compression, Static and dynamic shear compression, Static and dynamic torsion testing according to ASTM F2077, subsidence testing according to ASTM F2267, and expulsion testing according to ASTM Draft F04-25.02.02. Results demonstrate comparable mechanical properties to the predicate devices.
Conclusion	Non clinical performance testing demonstrate that the added SCARLET® AC-T spacer is substantially equivalent to its predicate devices in terms of intended use, material, design, mechanical properties and function.